K113704

JUN 2 8 2012

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name:

Abbott Laboratories Diagnostics Division
Dept. 9V6, AP5N-2
100 Abbott Park Road
Abbott Park, IL 60064

Contact person for all communications:

- Judith Wallach, ADD, Regulatory Affairs Project Manager
  Phone (847) 937-1132
  Fax (847) 937-4836
  E-Mail judith.r.wallach@abbott.com

or

- Grace LeMieux, ADD, Regulatory Affairs Director
  Phone (847) 935-0409
  Fax (847) 937-4836
  E-mail grace.lemieux@abbott.com

Device Name:

Reagent Kit
Classification Name: Hepatitis A virus (HAV) serological assays
Trade Name: ARCHITECT HAVAB-G (List No. 6L27)
Common Name: Hepatitis A Test (IgG Antibody)
Governing Regulation: 866.3310
Device Classification: II
Classification Panel: Microbiology
Code: LOL

Calibrator Kit
Classification Name: Calibrator
Trade Name: ARCHITECT HAVAB-G Calibrator Kit (List No. 6L27-01)
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: II
Classification Panel: Clinical Chemistry
Code: JIS

Control Kit
Classification Name: Quality control material (assayed and unassayed)
Trade Name: ARCHITECT HAVAB-G Control Kit (List No. 6L27-10)
Common Name: Control
Governing Regulation: 862.1660
Device Classification: I
Classification Panel: Microbiology
Code: MJY/MJX

Legally marketed device to which equivalency is claimed:

ARCHITECT HAVAB-M (k063329)

FDA Document Numbers of all prior related submissions (regardless of outcome):
ARCHITECT HAVAB-G Pre-IDE I00394

Intended Use of Device:

The ARCHITECT HAVAB-G assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric serum from patients with signs and symptoms or at risk for hepatitis. The ARCHITECT HAVAB-G assay is used to determine the immune status of individuals to hepatitis A virus infection.

Warning: This assay has not been FDA cleared or approved for the screening of blood or plasma donors. This assay cannot be used for the diagnosis of acute HAV infection.

Device Description:

The ARCHITECT HAVAB-G assay determines the presence of IgG anti-HAV in human serum. After an acute HAV infection, IgG anti-HAV levels rise quickly and may persist for life. The presence of IgG anti-HAV implies past HAV infection (recent or distant) or vaccination against HAV. Detectable levels above the assay cut-off suggest immunity to HAV infection. [1,2]

The ARCHITECT HAVAB-G assay is a two-step immunoassay for the qualitative detection of IgG anti-HAV in human serum using CMIA technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample, assay diluent, and hepatitis A virus (human) coated paramagnetic microparticles are combined. IgG anti-HAV present in the sample binds to the hepatitis A virus (human) coated microparticles. After washing, the anti-human IgG acridinium-labeled conjugate that is added in the second step binds to IgG anti-HAV. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). The presence or absence of IgG anti-HAV in the sample is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from an ARCHITECT HAVAB-G calibration. Specimens with signal to cutoff (S/CO) values

$\geq$ 1.00 are considered reactive for IgG anti-HAV. Specimens with S/CO values < 1.00 are considered nonreactive.

Comparison of Technological Characteristics:

The ARCHITECT HAVAB-G assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the qualitative detection of IgG anti-HAV in human adult and pediatric serum. The ARCHITECT HAVAB-M assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the qualitative detection of IgM anti-HAV in human serum and plasma.

The analytical performance of the ARCHITECT HAVAB-G assay was demonstrated through the following studies:

- Assay Cut-Off Determination
- Tube Type
- Sample Stability
- Sample On-Board Stability
- Within-Laboratory Precision (20-Day Precision)
- Analytical Specificity (Other Disease States)
- Interferences - Bilirubin, Hemoglobin, Protein, and Triglycerides
- Seroconversion Detection
- High Dose Hook Effect
- Reagent On-Board Drift
- Within-Assay Sample Carryover

Summary of Clinical Performance:

A total of 1147 specimens were obtained from collection centers and vendors in the United States and distributed among the three clinical centers to evaluate the performance of the ARCHITECT HAVAB-G compared to the HAV IgG Final Status as determined by ARCHITECT HAVAB-M and AxSYM HAVAB 2.0 assays. The following populations were studied: Individuals at increased risk of HAV infection, individuals with signs and symptoms of hepatitis, hepatitis A vaccine recipients, and surplus specimens from a pediatric population. The results are summarized in the table below.

Populations	Positive Percent Agreement (PPA)		Negative Percent Agreement (NPA)	
	PPA	95% Confidence Interval	NPA	95% Confidence Interval
Increased risk	94.49 (120/127)	88.97-97.76	100.00 (133/133)	97.26-100.00
Signs and symptoms	95.67 (265/277)	92.55-97.74	96.64 (230/238)	93.48-98.54
Vaccine Recipients	100.00 (48/48)	92.60-100.00	100.00 (2/2)	15.81-100.00
Surplus pediatric population #1	83.33 (10/12)	51.59-97.91	97.96 (96/98)	92.82-99.75
Surplus pediatric population #2	100.00 (72/72)	95.01-100.00	97.69 (127/130)	93.40-99.52
Surplus pediatric population total	97.62 (82/84)	91.66-99.71	97.81 (223/228)	94.96-99.28
Prospective pediatric population	66.67% (2/3)	9.43-99.16	100.00 (20/20)	83.16-100.00

Conclusions:

The results of the clinical performance studies, as determined by ARCHITECT HAVAB-M and AxSYM HAVAB 2.0 assays, and the analytical studies demonstrate that the ARCHITECT HAVAB-G assay is substantially equivalent to the ARCHITECT HAVAB-M assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories, Inc.
c/o Ms. Judith Wallach
100 Abbott Park Road
Dept. 09V6 AP5 North
Abbott Park, Illinois 60064-6095

JUN 2 8 2012

Re: K113704
Trade/Device Name: ARCHITECT HAVAB-G
ARCHITECT HAVAG-G Calibrator
ARCHITECT HAVAG-G Controls
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: Class II
Product Code: LOL, MJY, MJX, JIS
Dated: May 18, 2012
Received: May 18, 2012

Dear Ms. Wallach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Freddie Y. Poole
for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113704

Device Name: ARCHITECT HAVAB-G

ARCHITECT HAVAB-G Calibrator

ARCHITECT HAVAB-G Controls

Indications for Use:

ARCHITECT HAVAB-G

The ARCHITECT HAVAB-G assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric serum from patients with signs and symptoms or at risk for hepatitis. The ARCHITECT HAVAB-G assay is used to determine the immune status of individuals to hepatitis A virus infection.

Warning: This assay has not been FDA cleared or approved for the screening of blood or plasma donors. This assay cannot be used for the diagnosis of acute HAV infection.

Assay performance characteristics have not been established when the ARCHITECT HAVAB-G assay is used in conjunction with other hepatitis assays.

ARCHITECT HAVAB-G Calibrator:

The ARCHITECT HAVAB-G Calibrator is for the calibration of the ARCHITECT *i* System, when used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric serum from patients with signs and symptoms or at risk for hepatitis. The ARCHITECT HAVAB-G assay is used to determine the immune status of individuals to hepatitis A virus infection, using the ARCHITECT HAVAB-G Reagent Kit. The performance of the ARCHITECT HAVAB-G Calibrator has not been established with any other IgG anti-HAV assays.

HAVAB-G Controls:

The ARCHITECT HAVAB-G Controls are used for monitoring the performance of the ARCHITECT *i* System, when used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human adult and pediatric serum from patients with signs and symptoms or at risk for hepatitis. The ARCHITECT HAVAB-G assay is used to determine the immune status of individuals to hepatitis A virus infection, using the ARCHITECT HAVAB-G Reagent Kit. The performance of the ARCHITECT HAVAB-G Controls have not been established with any other IgG anti-HAV assays

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Tamara V. Feldblyum

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113704